

DOCKET NO.: ALLE0031-102
(16952 CON1-DIV11)
Serial No.: 10/621,978

PATENT

REMARKS

Upon entry of this response, claims 18, 21-29 will be pending in this application.

As a preliminary matter, Applicant wishes to thank Examiner Anish Gupta for the courtesy extended to Applicant's representative, Quan Nguyen, during a teleconference on May 10, 2006.

Terminal Disclaimers

(a) U.S. Patent No. 6,887,476

Claims 18 and 21-27 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 6,887,476 (hereinafter "the 476 patent").

Applicant hereby submits a terminal disclaimer under 37 C.F.R. 1.1321(c) with respect to the 476 patent for claims 18, 21, and 22-27 of the present application. Thus, the obviousness-type double patenting rejection should be withdrawn.

(b) U.S. Patent No. 6,113,915

Claims 18 and 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-16 of U.S. Patent No. 6,113,915 (hereinafter "the 915 patent").

Applicant hereby submits a terminal disclaimer under 37 C.F.R. 1.1321(c) with respect to the 915 patent for claims 18 and 21-29 of the present application. Thus, the obviousness-type double patenting rejection should be withdrawn.

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(c) U.S. Patent No. 6,235,289

Claims 18 and 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 6,235,289 (hereinafter "the 289 patent").

Applicant hereby submits a terminal disclaimer under 37 C.F.R. 1.1321(c) with respect to the 289 patent for claims 18 and 21-29 of the present application. Thus, the obviousness-type double patenting rejection should be withdrawn.

(d) U.S. Patent No. 6,333,037

Claims 18 and 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 6,333,037 (hereinafter "the 037 patent").

Applicant hereby submits a terminal disclaimer under 37 C.F.R. 1.1321(c) with respect to the 037 patent for claims 18 and 21-29 of the present application. Thus, the obviousness-type double patenting rejection should be withdrawn.

(e) U.S. Patent No. 6,372,226

Claims 18 and 21-29 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of U.S. Patent No. 6,372,226 (hereinafter "the 226 patent").

Applicant hereby submits a terminal disclaimer under 37 C.F.R. 1.1321(c) with respect to the 226 patent for claims 18 and 21-29 of the present application. Thus, the obviousness-type double patenting rejection should be withdrawn.

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Applicant asserts that the **terminal disclaimers are submitted for the sole purpose of administrative efficiency**, and Applicant respectfully disagrees that the pending claims are obvious over the 476, 915, 289, 037 patent and/or the 226 patent. (The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), MPEP §804.02 II).

Applicant respectfully disagrees that the pending claims are obvious over the disclosures of the cited patents because, for example, the claimed invention is directed to a method of treating arthritic pain by administering to a muscle. On the other hand, the cited patents disclose a method of treating pain by intraspinal administration (patent (b), (c) and (d) or intrathecal administration (e), which is administering to the central nervous system (CNS).¹ The teaching of administering botulinum toxin to the CNS to treat pain does not make the claimed invention obvious, because **the biological effects of administering botulinum toxin to the CNS is significantly different from that of administering to the muscle**. For example, when administered to the CNS the botulinum toxin primarily acts on nerve cells to modulate the neuronal communications between neurons in the spinal cord and/or brain. On the other hand, when administered to a muscle, the botulinum toxin primarily acts on motor neurons to modulate the contractility of the muscle. Neuronal communications between neurons in the spinal cord/brain and contractility of muscles are two entirely different biological processes. Accordingly, one of ordinary skill would not be motivated to change from modulating neuronal communications to modulating contractility of muscles to treat pain, much less arthritic pain.

¹ Intraspinal administration is administering the botulinum toxin within the vertebral canal or spinal cord, and intrathecal administration is administering botulinum toxin within a sheath, for example, cerebrospinal fluid that is contained within the dura matter.

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Thus, the claimed invention is not obvious over the disclosures of the cited patents.

Requirement to Show Common Ownership Is Satisfied with the Submission of the Terminal Disclaimers

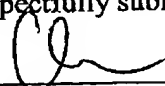
The Office Action states that patents (b) through (e) above may be cited as prior art if Applicant does not show that there is a common assignee for the present application and patents (b) through (e).

In a teleconference with Applicant's representative on May 10, 2006, Examiner Gupta stated that a submission of the terminal disclaimers with respect to patents (b) through (e) will satisfy the requirement for showing a common ownership of the present application and patents (b) through (e).

As Applicant is submitting herewith the terminal disclaimers, the requirement to show common ownership is satisfied.

In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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Date: May 11, 2006

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